

## **REMARKS**

### **Summary of the Office Action**

The foregoing Amendment and remarks which follow are responsive to the Office Action of April 6, 2006, issued in relation to the above-identified patent application. In that Office Action, the Examiner objected to the drawings as failing to comply with 37 CFR §1.83(a) for failure to “show every feature of the invention specified in the claims.” In addition, the Examiner rejected Claims 28, 34 and 35 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 18-21, 23-25, 27, 29, 32 and 33 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,630,196 issued to Bird et al. (hereinafter “BIRD”). Finally, the Examiner rejected Claims 22, 26, 30 and 31 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,193,532 issued to Moa et al. (hereinafter “MOA”).

### **Summary of the Amendment**

Applicant proposes to amend Claims 1, 22, 34 and 35 in order to clarify the invention. In addition, Applicant proposes to cancel Claim 31 and add new Claims 36-38 in order to clarify the invention and incorporate subject matter which is believed to be allowable over the relevant prior art references cited thereagainst. New Claim 36 is dependent upon Claim 35 and incorporates a limitation originally claimed in Claim 1.

New Claim 37 is also dependent upon Claim 35 and is similar in scope to originally-filed Claim 22. New Claim 38 is dependent upon Claim 35 and is similar in scope to originally-filed Claim 32. As such, the proposed amendments are not believed to add new matter nor necessitate

further searching. It is respectfully submitted that all claims are now believed to be in condition for allowance.

**Objections to the Drawings**

*The Examiner objected to the drawings under 37 CFR §1.83(a) as failing to “show every feature of the invention specified in the claims.”*

In the Office Action, the Examiner indicated that the feature of the “elongate tube in fluid communication with the exhaust channel” is not shown in the drawings. (Office Action, Page 2).

By this amendment, Applicant has cancelled Claim 31 regarding the feature of the “elongate tube in fluid communication with the exhaust channel” such that the objection advanced under 37 CFR §1.83(a) in relation to the drawings is now believed to be overcome.

**Rejection of Claims 28, 34 and 35 under 35 U.S.C. §112, first paragraph**

*Claims 28, 34 and 35 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.*

In the Office Action, the Examiner indicated that “newly added Claims [28, 34 and 35] have limitations which lack support from the originally filed specification.” The Examiner indicated that the limitations of “exhaust channels [being] substantially linear and intersect[ing] one another at an angle of at least 90 degrees” as claimed in Claim 28 constitutes new matter. The Examiner further indicates that the feature of “the inlet channel [being] approximately one-fourth the cross-sectional area of at least one of the breathing and exhaust channels” as claimed in Claim 34 and the feature of “the axis of the gas inlet channel [being] directed towards an elbow disposed at an inner edge of [a]

junction between the breathing and exhaust channels” as claimed in Claim 35 also constitute new matter. (Office Action, Page 3).

**Claim 28**

Applicant submits that Claims 28 and 34 fulfill the enablement requirement under 35 U.S.C. §112, first paragraph. For example, the feature of the “breathing and exhaust channels [being] substantially linear” as claimed in Claim 28 is fully disclosed in the drawings as originally filed. More specifically, as can be seen in Figures 1, 2a-2c, 9a-9e, and 10a-10e, each of the breathing and exhaust channels is clearly shown as being linear in nature. Furthermore, Applicant submits that the feature of the “breathing and exhaust channels...intersecting one another at an angle of at least about 90 degrees” as claimed in Claim 28 is also supported in the figures. More specifically, in Figures 1 and 2a-2c, the breathing channel (2) and the exhaust channel (4) are shown as intersecting one another at an angle of about 135 degrees. In addition, Figures 9a-9e and 10a-10e clearly illustrate the breathing channel (2) intersecting the exhaust channel (4) at an angle of about 90 degrees. As such, Applicant submits that adequate support is provided in the specification as originally filed for the features claimed Claim 28.

**Claim 34**

Regarding the 35 U.S.C. §112 rejection advanced in relation to Claim 34, Applicant submits that the feature of the “cross-sectional area of the gas inlet channel [being] approximately one-fourth the cross-sectional area of at least one of the breathing and exhaust channels” as claimed in Claim 34 is fully supported in the figures as originally filed. More specifically, the gas inlet channel (8) is illustrated with a scaled width of approximately 0.219 inches. Likewise, the breathing channel (2) is illustrated in Figure 1 at a scaled width of approximately 0.875 inches. Both measurements of the

breathing channel (2) and the gas inlet channel (8) are taken at the same scale. The ratio of the width of the gas inlet channel (0.219 inches) to the breathing channel (0.875 inches) is 0.25 which is the equivalent to the ratio of “one-fourth” as recited in Claim 34. As such, Applicant submits that adequate support is provided in the specification as originally filed for the features claimed in Claim 34.

#### **Claim 35**

Lastly, Applicant submits that the Examiner’s rejection of Claim 35 under 35 U.S.C. §112, first paragraph, regarding the feature of the “axis of the gas inlet channel is directed toward an elbow disposed at an inner edge of [the] junction between the breathing and exhaust channels” is overcome due to the Applicant’s amendment of Claim 35 deleting the feature of the “elbow.” More specifically, Claim 35 has been amended to now recite the feature of the “axis of the gas inlet channel is directed towards an inner edge of the junction between the breathing and exhaust channels.” As can be seen in Figure 1, the axis (12) of the gas inlet channel (8) is clearly shown as being directed toward an inner edge of the junction of the breathing channel (2) and the exhaust channel (4). Due to the deleted reference to the “elbow” in Claim 35, the rejection under 35 U.S.C. §112, first paragraph, is now believed to be overcome. In summary, Applicant believes that the Examiners’ rejections of Claims 28, 34 and 35 under 35 U.S.C. §112, first paragraph are overcome and that Claims 28, 34 and 35 are now believed to be allowable.

#### **Rejection of Independent Claim 1 Under 35 U.S.C. §102(b)**

*In the Office Action, Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by BIRD. More particularly, the Examiner indicated that the breathing device illustrated in the*

*drawings and disclosed in the specification of BIRD anticipates independent Claim 1 of the application.*

The Examiner indicates that “BIRD discloses a breathing device (11) comprising and in fluid communication, a breathing channel (23) and an exhaust channel (at 53) extending from a junction therebetween; and a gas inlet channel (42, 81, 82) arranged so as in use to introduce gas into said breathing channel such that in use a positive pressure may be maintained in the breathing channel, wherein an axis of the said gas inlet channel is laterally offset from an axis of the breathing channel at the point at which the gas inlet channel introduces the gas into the breathing channel (Figures 4, 5).” (Office Action, Page 4).

**BIRD discloses a manually-operated exhalation valve**

Importantly, the apparatus of the BIRD requires a “manually operated exhalation valve...mounted on the body for controlling inhalation and exhalation phases in the device.” (Col. 1; lines 26-28). Furthermore, the BIRD device includes “flow passages [that are] axially aligned to the laminar flow of the gasses through the device.” (Col. 1; lines 29-32). Finally, the BIRD device is understood to provide for “less tendency for turbulent precipitation or premature fallout of the nebulized particles in the airflow passages.” In this regard, Applicants submit that the BIRD device provides a means for administering medication by atomizing liquid or subsequent inhalation in the patient wherein the “breathing device...now makes it possible to create a main stream of gasses which sweep nebulized particles directly toward the patient’s airway.” (Col. 4; lines 37-41).

Applicants wish to emphasize that BIRD is understood to disclose a device that requires “the patient, to start the treatment,...as he begins to inhale,...presses the center portion of the valve

member 54 downwardly to start the inhalation phase as shown in Figure 4. This valve member is held down by the patient until the lungs are filled. As soon as the lungs have been filled and the patient desires to exhale the valve member is released by the patient permitting the exhaled gasses to exhaust to the atmosphere as shown in Figure 5.” (Col. 3; lines 57-67). As such, Applicants understand BIRD to require “patient...control [of] the inhalation and exhalation phases merely by operation of the button valve member.” (Col. 4; lines 42-45).

In contrast, the present application discloses a breathing device wherein the control of the gas flow therewithin is effectuated *solely* through the internal geometry of the gas inlet channel 8 relative to the breathing channel 2 and exhaust channel 4. More specifically, as can be seen in Figures 2a-2c of the application, control of the flow of gas in Applicants’ invention is effectuated *solely* due to the lateral offset of the gas inlet channel 8 with respect to the breathing channel 2 and the exhaust channel 4.

In this regard, Applicants respectfully submit that BIRD is silent with regard to teaching an apparatus for supplying a breathing gas to a patient wherein a flow of supply gas therewithin is effectuated solely through the internal geometry of the gas inlet channel relative to the breathing and exhaust channels. More specifically, nowhere in BIRD is there disclosed either in the drawings or the specification a means to “introduce gas into said breathing channel such that...a positive pressure may be maintained in the breathing channel” as recited in amended Claim 1 of the application without the use of the button-like valve member 54 as illustrated in Figures 4 and 5 of BIRD.

**BIRD fails to disclose a laterally offset gas inlet channel**

In addition, Applicant submits that BIRD is not understood to disclose the feature of a “gas

inlet channel [being] laterally offset from an axis of the breathing channel at the point at which the gas inlet channel introduces the gas into the breathing channel” as is recited in amended Claim 1 of the application. For example, as shown in Figures 4 and 5 of BIRD, “jet nozzle 29...has [a] discharge end in axial alignment with a venturi like passage 27.” (Col. 2; lines 25-26). As can be seen in Figures 4 and 5, “line 82 [is connected] to the jet nozzle 29.” (Col. 3; lines 37-38). As such, the combination of jet nozzle 29 and line 82 in BIRD, indicated by the Examiner as being the functional equivalent of the gas inlet channel 8 of the application, is not “laterally offset from an axis of the breathing channel” as is recited in amended Claim 1.

Furthermore, Applicants submit that jet nozzle 42 shown in Figures 4 and 5 of BIRD, and indicated by the Examiner as being the functional equivalent of the gas inlet channel 8 of the application, is also not understood to be “laterally offset from an axis of the breathing channel at the point at which the gas inlet channel introduces the gas into the breathing channel,” in the same manner as that provided in the application. More specifically, Figures 4 and 5 of BIRD illustrate the “ball 43 is...mounted...opposite the jet nozzle 42 so that any liquid which is drawn up through the capillary tube 41 is broken up into small particles which pass into the main air stream and through the passages 38 and 39.” (Col. 2; lines 44-47). In this regard, Applicants submit that the axis of jet nozzle 42 as shown in Figures 4 and 5 of BIRD is oriented in intersecting relationship with saddle 23 (indicated by the Examiner as being the functional equivalent of the breathing channel). On the contrary, as shown in Figures 1 and 2a-2c of the application, gas inlet channel 8 is laterally offset from the axis of the breathing channel 2.

As such, Applicants respectfully submit that BIRD is silent with regard to teaching a device for supplying a breathing gas to a patient wherein the gas inlet channel is laterally offset from the

axis of the breathing channel. More specifically, nowhere in BIRD is there understood to be disclosed either in the drawings or the specification the feature of orienting “an axis of the gas inlet channel...laterally offset from an axis of the breathing channel” such that “a positive pressure may be maintained in the breathing channel” as claimed in amended Claim 1 of the application.

To the contrary, jet nozzle 29 is disclosed and illustrated in Figures 4 and 5 as being in axial alignment with the saddle 23. Furthermore, jet nozzle 29 is indicated as being provided for the purpose of “causing additional atmospheric air to be drawn in through the side passages 31 through the venturi passage 27 where they are introduced to the main stream flow passages 38 and 39 in the micronebulizer.” (Col. 4; lines 2-5).

As was earlier mentioned, jet nozzle 42 is also not understood to be oriented in laterally offset relationship with the axis of the breathing channel for maintaining positive pressure in the breathing channel. To the contrary, as was earlier mentioned, the axis of jet nozzle 42 is understood to be disposed in intersecting relationship with the axis of saddle 23 (functional equivalent of the breathing channel 2). In addition, “jet nozzle 42 causes the medication to be drawn up through the capillary tube 41 where it is broken up into small particles by the ball 43 and entrained in the main stream air flow where it passes directly through the saddle 23 and...into the lungs of the patient” Col. 4; ll 6-10) and not for the purposes of maintaining a positive pressure in the breathing channel as is provided in the Applicants’ invention.

Therefore, Applicants respectfully submit that BIRD teaches away from the breathing device disclosed in the Applicants’ invention. As such, amended independent Claim 1 of the application is believed to distinguish over BIRD such that the §102(b) rejection advanced by the Examiner should be withdrawn. In addition, previously presented independent Claim 35, which is similar in scope to



Claim 1 but a narrower version thereof, is also believed to distinguish over BIRD. As such, amended independent Claim 1 as well as amended independent Claim 35 are now believed to be in condition for allowance. Likewise, all claims depending therefrom, namely dependent Claims 18-30 and 32-34 as well as new dependent Claims 36-38 are also believed to be in condition for allowance.

**Rejection Under 35 U.S.C. §103(a)**

*In the Office Action, Claims 22, 26, 30 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over MOA (indicated in the Office Action as BIRD et al.).*

In the Office Action, the Examiner notes that “the difference between [MOA] and Claim 22 is the location of the gas inlet open into the junction between the breathing channel and the exhaust channel on an outer side of the junction” and that “it would have been an obvious matter of design consideration...to have the location of the gas inlet open into the junction.” With respect to Claim 26, the Examiner indicates that “[MOA] does not disclose that the gas inlet is moveable. It would have been obvious...to use a bendable material to allow movement of the gas inlet.” Furthermore, with respect to Claim 30, the Examiner indicates that “[MOA] does not disclose the use of a mask. However, it is well known in the art that nasal prongs can be substituted for the mask...as a design consideration.” Finally, with respect to Claim 31, the Examiner notes that [MOA] “does not disclose a tube in fluid communication with exhaust channel. It would have been an obvious matter of design consideration...to have a tube off the exhaust channel to allow the exhaust air to be collected.” (Office Action, Pages 6-7).

By this amendment, Claim 36 is cancelled such that the rejection advanced in relation thereto is now moot. With regard to Claims 22, 26 and 30, as was mentioned above, Applicants submit that

MOA fails to disclose a breathing device wherein “an axis of the gas inlet channel is laterally offset from an axis of the breathing channel at the point at which the gas inlet channel introduces the gas into the breathing channel” as is recited in amended Claim 1. More specifically, Figures 1-3 of MOA disclose “first branch channel [11] [being] essentially coaxially [with] an inlet channel 13 for fresh gas.” (Col. 2; lines 50-51). Furthermore, MOA specifically recites that “inlet channel is connected to the second branch channel 12 and thus directs the stream of fresh gas essentially coaxially into the first branch channel [11].” (Col. 2; lines 53-56).

As such, Applicants submit that MOA fails to disclose the feature of the gas inlet channel (the functional equivalent of the inlet channel 13 of MOA) being laterally offset from an axis of the breathing channel (the functional equivalent of the first branch channel 11 of MOA). Therefore, Applicants respectfully submit that MOA teaches away from the breathing device disclosed in the Applicants’ invention. Accordingly, it is submitted that because MOA fails to disclose or suggest at least the above noted features of the present invention, no proper combination of design features in combination with Claims 22 and 30 nor the selection of material in Claim 26 in combination with MOA can render unpatentable the asserted combination of features recited in at least independent Claim 1. Therefore, Applicants submit that there is insufficient motivation for the proposed modifications asserted by the Examiner with regard to Claims 22, 26 and 30 such that a *prima facie* case of obviousness is not established and the rejections are believed to be traversed.

### **Conclusion**

In view of the foregoing, the present application is believed to be in condition for allowance. Entry of the amendment and issuance of a Notice of Allowance is therefore respectfully requested.

Should the Examiner have any suggestions for expediting allowance of the application, please contact Applicant's representative at the telephone number listed below.

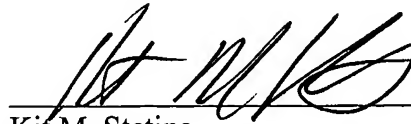
If any additional fees are required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

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5/11/06

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